K121020

MAY - 3 2012

510(K) SUMMARY

A. Submitter Information

DePuy Spine, Inc.
325 Paramount Drive
Raynham, MA 02767

Contact Person:	Kirsten Lehmuller
Address:	325 Paramount Drive Raynham, MA 02767
Telephone number:	(508) 828-3291
Fax number:	(508) 828-3797
Email:	klehmull@its.jnj.com

B. Date Prepared May 2, 2012

C. Device Class Class III

D. Device Name

Trade/Proprietary Name:	VIPER® Systems
Common/Usual Name:	Pedicle Screw Spinal System
Classification Name:	Spinal interlaminar fixation orthosis per 21 CFR §888.3050 Pedicle screw spinal fixation per 21 CFR §888.3070
Classification Panel:	Orthopaedics
FDA Panel Number:	87

E. Product Code(s): NKB, KWP, MNH, MNI

DK 5/3

F. Predicate Device Name

Trade name: DePuy Spine VIPER® Spinal System (K102701)
DePuy Spine VIPER® System (K111571)

G. Device Description

The VIPER® System is a 5.5mm rod system offered in both stainless steels and titanium materials. The system consists of monoaxial screws, polyaxial screws, uni-planar screws, and extended tab implants. They are available in various geometries and sizes to accommodate patient anatomy.

H. Intended Use

The VIPER systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities of deformities of the thoracic, lumbar, and sacral spine.

The VIPER System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma(i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudoarthrosis; and failed previous fusion in skeletally mature patients.

When used in a percutaneous, posterior approach with MIS instrumentation, the VIPER Systems are intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma(i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudoarthrosis; and failed previous fusion in skeletally mature patients.

I. Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use

The proposed modifications to the DePuy Spine VIPER® Systems are identical to predicate devices (K111571) except for the addition of fully threaded and partially threaded favored angle polyaxial screws in various sizes to the systems,

which are outside the range of the currently cleared screw offerings. The design, materials, and technology remain identical to the predicate systems.

J. Materials

Manufactured from ASTM F 138 implant grade stainless steel, ASTM F 139 implant grade stainless steel, and ASTM F 136 implant grade titanium alloy.

K. Performance Data

Performance data in the form of an engineering rationale that included Finite Element Analysis was conducted to prove there was no new worst case component for the proposed VIPER System's components contained in this notification.

L. Conclusion

Both the engineering rationale that included Finite Element Analysis and the Substantial Equivalence Justification demonstrate that the device is as safe, as effective, and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DePuy Spine, Incorporated
% Ms. Kirsten Lehmuller
Regulatory Affairs Associate
325 Paramount Drive
Raynham, Massachusetts 02767

MAY - 3 2012

Re: K121020
Trade/Device Name: VIPER® Systems
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWP
Dated: April 3, 2012
Received: April 4, 2012

Dear Ms. Lehmuller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin C. Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K121020

Device Name: VIPER® Systems

Indications For Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use ___ ___

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121020